

REMARKS

Claims 1, 2, 4, 8, 12, 13, 15, 17, 20, 28, 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61, 64, 66, 67 and 69-78 are now in the application. Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61, 64, 66, 67 and 69-78 are directed to the elected invention. Claims 1, 2, 4, 8, 12, 13, 15, 17, 20, and 28 are directed to non-elected invention and may be cancelled by the examiner upon the allowance of the claims directed to the elected invention. Claim 29 has been amended to include recitations from claim 62 along with modifying language concerning the claimed Markush group. Accordingly, claim 62 has been cancelled without prejudice or disclaimer. Claim 29 has also been amended to recite “a content” in place of “the content”. The amendments to the claims do not introduce any new matter nor raise any new issues. As a minimum, they reduce the issues for Appeal.

The rejection of claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61, 62, 64, 66, 67, and 69-78 under 35 USC 112, second paragraph has been overcome by the above amendments to the claims. In particular, claim 29 has been amended to clarify the term “fat and oil component” by reciting “fat or oil component”. Also, the Markush group of the fat or oil has been properly and clearly recited in claim 29. The amendment to recite “a content” addresses the lack of antecedent basis rejection.

Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61, 62, 64, 66, 67, and 69-78 were rejected under 35 USC 103(a) as being obvious WO 01/52822 to Chopra in view of US Patent 4,751,241 to Motoyama et al. The cited references do not render obvious the present invention.

As disclosed on page 4, line 35 to page 5, line 24 in the specification, the composition of the present invention can have simultaneously both good stability of reduced coenzyme Q₁₀ and a high-level absorbability in a living body. First of all, the present inventors found that reduced coenzyme Q₁₀ is protected against oxidation by molecular oxygen and stabilized in a surprisingly favorable manner in the presence of a fat and/or oil component and/or a polyol without preparing any complicated and troublesome composition. Secondly, the present inventors also found the

following: while the addition of Tween and Span species (surfactants (emulsifiers)) in wide use markedly decreases the above-mentioned reduced coenzyme Q₁₀-stabilizing effect of a fat and/or oil component and/or polyol, the addition of polyglycerol fatty acid esters surprisingly has little influence on the stabilizing effect of the fat and/or oil component and/or polyol and such esters serve as very favorable surfactants (emulsifiers). Namely, the addition of the polyglycerol fatty acid ester enhances absorbability of reduced coenzyme Q₁₀ in the living body without inhibiting the reduced coenzyme Q₁₀-stabilizing effect of the fat and oil component and/or polyol so that reduced coenzyme Q₁₀ can be stably maintained.

As appreciated by the Examiner, Chopra does not disclose the reduced coenzyme Q₁₀-containing composition comprising the polyglycerol fatty acid ester of the present invention. In addition, the components other than the polyglycerol fatty acid ester in the composition of the present invention also differ from those in Chopra. Since the composition of Chopra contains a large quantity of Vitamin E or Tween/Span, the composition cannot stably maintain reduced coenzyme Q₁₀ without a reducing agent. Thus, the composition of Chopra stably maintains reduced coenzyme Q₁₀ by using a reducing agent. On the other hand, by including the fat and/or oil component and/or the polyol, the composition of the present invention can stably maintain reduced coenzyme Q₁₀ whether or not the composition contains a reducing agent. Thus, Chopra neither discloses nor suggests that the composition of the present invention can stably maintain reduced coenzyme Q₁₀ by using the fat and/or oil component and/or the polyol.

Motoyama does not overcome the above discussed deficiencies of Chopra with respect to rendering obvious the present invention. Motoyama only describes coenzyme Q₁₀ (ubidecarenone: oxidized coenzyme Q₁₀) on column 2, lines 55-56 and does not describe reduced coenzyme Q₁₀. Thus, since Motoyama uses oxidized coenzyme Q₁₀, which is already oxidized, Motoyama does not intend at all to maintain reduced coenzyme Q₁₀ stable with protecting it against oxidation. Moreover, Motoyama only describes that the polyglycerol ester of an unsaturated fatty acid is used in order to facilitate the absorptivity of the drug. As mentioned on page 10 of the Office Action, in Motoyama, the dispersibility of drug formulations is stabilized by use of the polyglycerol fatty acid ester. Thus, Motoyama neither discloses nor suggests the effects

of the present invention, in which reduced coenzyme Q₁₀ is stabilized against oxidation in the presence of a fat and/or oil component and/or a polyol and the addition of the polyglycerol fatty acid ester barely inhibits the reduced coenzyme Q₁₀-stabilizing effect of the fat and oil component and/or polyol.

As shown in the attached Declaration, in the composition containing polyglycerol fatty acid and not higher than 30% by weight of Tween80 high stability of reduced coenzyme Q₁₀ was achieved, but in the composition containing higher than 30% by weight of Tween80 the stability of reduced coenzyme Q₁₀ was extremely inhibited. In addition, as shown in Examples 23-24 in the present specification, the composition containing no Tween80 also shows high stability of reduced coenzyme Q₁₀. However, Chopra and Motoyama neither disclose nor suggest such excellent effects of the present invention. This Declaration was not earlier presented since it was believed that the prior filed Declaration was sufficient to demonstrate the patentability of the present invention.

As mentioned above, the combination of Chopra and Motoyama neither discloses nor suggests that the composition can simultaneously have both good stability of reduced coenzyme Q₁₀ and a high-level absorbability in a living body by the specific constitution of the present invention. Consequently, the present invention would not have been suggested to one skilled in the art from the combination of Chopra and Motoyama, and it is unobvious.

Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61, 62, 64, 66, 67, and 69-78 were provisionally rejected on the grounds of non-statutory obviousness-type double patenting over claims 16-19 of application SN 11/586,511. Claim 29 recites the amounts of vitamin E and Tween and/or Span, which are not recited in claim 16 of SN 11/586,511. Accordingly, it is requested that this rejection be withdrawn. This rejection will be addressed once the other rejections have been overcome.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Please charge any fees due with this paper to our Deposit Account No. 22-0185, under Order No. 21581-00490-US from which the undersigned is authorized to draw.

Dated: October 23, 2009

Respectfully submitted,

Electronic signature: /Burton A. Amernick/
Burton A. Amernick
Registration No.: 24,852
CONNOLLY BOVE LODGE & HUTZ LLP
1875 Eye Street, NW
Suite 1100
Washington, DC 20006
(202) 331-7111
(202) 293-6229 (Fax)
Attorney for Assignee